Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4611
cchevalier@gibbonslaw.com

Of Counsel:
David I. Berl
Elise M. Baumgarten
Kevin Hoagland-Hanson
Falicia Elenberg
Nicholas Vincent
Max Accardi
WILLIAMS & CONNOLLY LLP
680 Maine Avenue, SW
Washington, DC 20024
(202) 434-5000
dberl@wc.com
ebaumgarten@wc.com
khoagland-hanson@wc.com
felenberg@wc.com
nvincent@wc.com
maccardi@wc.com

Counsel for Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, KuDOS Pharmaceuticals Limited, and MSD International Business GmbH

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, ASTRAZENECA AB, KUDOS PHARMACEUTICALS LIMITED, and MSD INTERNATIONAL BUSINESS GMBH *Plaintiffs*, v. CIPLA LIMITED and CIPLA USA, INC., *Defendants*.	Civil Action No. 24-8167 **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, KuDOS Pharmaceuticals Limited, and MSD International Business GmbH (collectively, "Plaintiffs"), by their attorneys, file this Complaint against Defendants Cipla Limited and Cipla USA, Inc. (collectively, "Cipla"), and allege the following:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq*., which arises out of the submission by Cipla of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of LYNPARZA® (olaparib) tablets, 100 mg and 150 mg, prior to the expiration of U.S. Patent No. 12,048,695 (the "'695 patent").

2. Cipla notified Plaintiffs by letter dated May 21, 2024 ("Cipla's Notice Letter") that it had submitted to FDA ANDA No. 219410 ("Cipla's ANDA"), seeking approval from FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic olaparib tablets, 100 mg and 150 mg, ("Cipla's ANDA Product") prior to the expiration of U.S. Patent Nos. 8,859,562, 8,475,842, and 11,633,396.

3. Plaintiffs filed suit against Cipla in this District, asserting that Cipla's ANDA infringes of U.S. Patent No. 8,859,562 ("the '562 patent"); U.S. Patent No. 11,970,530 (the "'530 patent"); U.S. Patent No. 11,975,001 (the "'001 patent"); U.S. Patent No. 8,475,842 ("the '842 patent"); and U.S. Patent No. 11,633,396 ("the '396 patent"). *See AstraZeneca Pharms. L.P. v. Cipla Limited*, Civ. No. 24-7346, Dkt. No. 1. That suit is currently pending in this District.

The Parties

4. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord

Pike, Wilmington, Delaware 19803. AstraZeneca Pharmaceuticals LP is the holder of New Drug Application No. 208558 for the manufacture and sale of LYNPARZA® (olaparib) tablets.

5. Plaintiff AstraZeneca UK Limited is a private company limited by shares organized and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom.

6. Plaintiff AstraZeneca AB is a limited company organized and existing under the laws of Sweden, whose registered office is at SE-151 85, Södertälje, Sweden.

7. Plaintiff KuDOS Pharmaceuticals Limited is a private company limited by shares organized and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom.

8. Plaintiff MSD International Business GmbH is a company with limited liability organized and existing under the laws of Switzerland, whose registered office is at Tribschenstrasse, 60, 6005 Lucerne, Switzerland.

9. On information and belief, Defendant Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business in Warren, New Jersey. On information and belief, Cipla USA, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

10. On information and belief, Cipla USA, Inc. is a wholly owned subsidiary of Cipla Limited and is controlled by Cipla Limited.

11. On information and belief, Cipla Limited and Cipla USA, Inc. acted in concert to prepare and submit Cipla's ANDA to the FDA.

12. On information and belief, Cipla Limited and Cipla USA, Inc. know and intend that upon approval of Cipla's ANDA, Cipla Limited will manufacture Cipla's ANDA Product and Cipla

Limited and Cipla USA, Inc. will directly or indirectly market, sell, and distribute Cipla's ANDA Product throughout the United States, including in New Jersey.

13. On information and belief, following any FDA approval of Cipla's ANDA, Cipla Limited and Cipla USA, Inc. will act in concert to distribute and sell Cipla's ANDA Product throughout the United States, including in New Jersey.

Jurisdiction

14. Plaintiffs incorporate each of the preceding paragraphs 1–13 as if fully set forth herein.

15. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

16. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Cipla Limited and Cipla USA, Inc.

17. Cipla Limited and Cipla USA, Inc. are subject to personal jurisdiction in New Jersey because, among other things, Cipla Limited and Cipla USA, Inc. have purposefully availed themselves of the benefits and protections of New Jersey's laws such that those entities would reasonably anticipate being haled into court here. On information and belief, Cipla Limited and Cipla USA, Inc. develop, manufacture, import, market, offer to sell, and/or sell generic drugs throughout the United States, including in the State of New Jersey, and therefore transact business within the State of New Jersey related to Plaintiffs' claims, and/or have engaged in systematic and continuous business contacts within the State of New Jersey.

18. In addition, this Court has personal jurisdiction over Cipla Limited and Cipla USA, Inc. because, among other things, on information and belief: (1) Cipla USA, Inc. filed Cipla's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for

sale, sale, and/or importation of Cipla's ANDA Product in the United States, including in New Jersey; and (2) upon approval of Cipla's ANDA, Cipla Limited and Cipla USA, Inc. will directly, or indirectly through subsidiaries, intermediaries, distributors, retailers, or others, market, distribute, offer for sale, sell, and/or import Cipla's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Cipla's ANDA Product in New Jersey. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Cipla's ANDA, Cipla's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

19. This Court has personal jurisdiction over Cipla Limited and Cipla USA, Inc. because those entities (1) engage in patent litigation concerning Cipla's products in this District, and (2) do not contest personal jurisdiction in this District. *See, e.g.*, *Cubist Pharms. LLC v. Cipla USA, Inc. and Cipla Limited*, Civ. No. 19-12920, Dkt. No. 15 (D.N.J. July 2, 2019).

20. Additionally, this Court has personal jurisdiction over Cipla USA, Inc. because, on information and belief, Cipla USA, Inc. maintains its principal place of business in this District.

21. For the above reasons, it would not be unfair or unreasonable for Cipla Limited and Cipla USA, Inc. to litigate this action in this District, and the Court has personal jurisdiction over those entities here.

Venue

22. Plaintiffs incorporate each of the preceding paragraphs 1–21 as if fully set forth herein.

23. Venue is proper in this District as to Cipla Limited pursuant to 28 U.S.C. § 1391, at least because, on information and belief, Cipla Limited is a foreign corporation that may be sued in any judicial district in which it is subject to the Court's personal jurisdiction.

24. Venue is proper in this District as to Cipla USA, Inc. pursuant to 28 U.S.C. § 1400(b), at least because, on information and belief, Cipla USA, Inc. has committed, or will commit, an act of infringement in this District, and has a regular and established place of business in this District. On information and belief, among other things, (1) Cipla filed Cipla's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product in the United States, including in New Jersey; and (2) upon approval of Cipla's ANDA, Cipla will market, distribute, offer for sale, sell, and/or import Cipla's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Cipla's ANDA Product in New Jersey. Further, on information and belief, Cipla USA, Inc. maintains its principal place of business in this District.

25. Venue is proper in this District as to Cipla Limited and Cipla USA, Inc. because those entities (1) engage in patent litigation concerning Cipla's products in this District, and (2) do not contest that venue is proper in this District. *See, e.g.*, *Cubist Pharms. LLC v. Cipla USA, Inc. and Cipla Limited*, Civ. No. 19-12920, Dkt. No. 15 (D.N.J. July 2, 2019).

Factual Background

26. LYNPARZA® is approved by FDA for the treatment of certain ovarian, breast, pancreatic, and prostate cancers. The active pharmaceutical ingredient in LYNPARZA® is olaparib, a poly (ADP-ribose) polymerase (PARP) inhibitor.

27. In Cipla's Notice Letter, Cipla states that the subject of Cipla's ANDA is olaparib tablets, 100 mg and 150 mg. In Cipla's Notice Letter, Cipla states that Cipla's ANDA was submitted under 21 U.S.C. § 355(j)(1) and § 355(j)(2)(A) and contends that Cipla's ANDA contains

bioavailability and/or bioequivalence studies for Cipla's ANDA Product. On information and belief, Cipla's ANDA Product is a generic version of LYNPARZA®.

28. The purpose of Cipla's submission of Cipla's ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product.

29. In Cipla's Notice Letter, Cipla stated that it had submitted Paragraph IV Certifications to FDA alleging that the '562, '842, and '396 patents were invalid, unenforceable, and/or not infringed, and that Cipla is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '562, '842, and '396 patents.

30. Following receipt of Cipla's Notice Letter, on February 2, 2024, Plaintiffs filed suit against Cipla alleging that Cipla's ANDA infringes certain patents, including the '562, '530, '001, '842, and '396 patents. *See AstraZeneca Pharms. L.P. v. Cipla Limited*, Civ. No. 24-7346, Dkt. No. 1. That suit is currently pending in this District.

31. On information and belief, Cipla has not challenged U.S. Patent No. 8,143,241 or U.S. Patent No. 8,071,579, which are listed in connection with LYNPARZA® in the FDA's Orange Book and expire on August 12, 2027. On information and belief, Cipla has not challenged U.S. Patent No. 7,449,464, which is listed in connection with LYNPARZA® in the FDA's Orange Book and expires on September 8, 2027. On information and belief, following the expiration of those patents, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

32. On July 10, 2024, the U.S. Patent and Trademark Office issued an Issue Notification for the '695 patent, and indicated that the '695 patent would issue on July 30, 2024.

33. On July 26, 2024, Plaintiffs notified Cipla's outside counsel of the upcoming issuance of the '695 patent. Plaintiffs also indicated that they anticipated that Cipla would file a Paragraph IV Certification to FDA alleging the '695 patent is invalid, unenforceable, and/or not infringed, and that Cipla would seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '695 patent. Plaintiffs received no substantive response from Cipla as of the date of this Complaint.

34. On information and belief, Cipla intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '695 patent.

Count I – Infringement of the '695 Patent Under 35 U.S.C. § 271(e)(2)

35. Plaintiffs incorporate each of the preceding paragraphs 1–34 as if fully set forth herein.

36. On July 30, 2024, the United States Patent and Trademark Office (the "USPTO") duly and lawfully issued the '695 patent, entitled "Methods of Treating Homologous Recombination Deficient Cancer." A copy of the '695 patent is attached hereto as Exhibit A.

37. Plaintiff KuDOS Pharmaceuticals Limited is the assignee of the '695 patent. Plaintiffs collectively possess all exclusive rights and interests in the '695 patent.

38. The '695 patent claims, *inter alia*, an immediate-release pharmaceutical composition in the form of a solid dispersion comprising 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl-]-2H-Phthalazin-1-One, known by the international nonproprietary name olaparib, and certain excipients, that meets certain stability testing parameters.

39. LYNPARZA® contains olaparib as its active pharmaceutical ingredient.

40. LYNPARZA® is covered by at least one claim of the '695 patent, and the '695 patent will be listed in connection with LYNPARZA® in the FDA's Orange Book.

41. On information and belief, following the expiration of those patents that Cipla chose not to challenge, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

42. Cipla received notice of the '695 patent at least as of July 26, 2024, when Plaintiffs notified Cipla's outside counsel of the upcoming issuance of the '695 patent.

43. On information and belief, Cipla intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '695 patent.

44. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '695 patent was an act of infringement of the '695 patent under 35 U.S.C. § 271(e)(2)(A).

45. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '695 patent, either literally or under the doctrine of equivalents.

46. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '695 patent.

47. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '695 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

48. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '695 patent and that

Cipla's ANDA Product and its proposed labeling is not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '695 patent after approval of Cipla's ANDA.

49. The foregoing actions by Cipla constitute and/or will constitute infringement of the '695 patent, active inducement of infringement of the '695 patent, and contribution to the infringement by others of the '695 patent.

50. On information and belief, Cipla has acted with full knowledge of the '695 patent and without a reasonable basis for believing that it would not be liable for infringing the '695 patent, actively inducing infringement of the '695 patent, and contributing to the infringement by others of the '695 patent.

51. Unless Cipla is enjoined from infringing the '695 patent, actively inducing infringement of the '695 patent, and contributing to the infringement by others of the '695 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count II – Declaratory Judgment of Infringement of the '695 Patent

52. Plaintiffs incorporate each of the preceding paragraphs 1–51 as if fully set forth herein.

53. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Cipla on the other regarding validity and/or infringement of the '695 patent.

54. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Cipla's ANDA Product with its proposed labeling, or any other Cipla drug product that is covered by or whose use is covered by the '695 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '695 patent, and that the claims of the '695 patent are valid and enforceable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

1. A judgment that the ’695 patent has been infringed under 35 U.S.C. § 271(e)(2) by Cipla’s submission to the FDA of Cipla’s ANDA;
2. A judgment that the ’695 patent is valid and enforceable;
3. A judgment pursuant to 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval of Cipla’s ANDA and for Cipla to make, use, offer for sale, sell, market, distribute, or import Cipla’s ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the ’695 patent, shall not be earlier than the expiration date of the ’695 patent, inclusive of any extension(s) and additional period(s) of exclusivity.
4. A preliminary and permanent injunction pursuant to 35 U.S.C. § 371(e)(4)(B) enjoining Cipla, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Cipla’s ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the ’695 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’695 patent, inclusive of any extension(s) and additional period(s) of exclusivity;
5. An order pursuant to this Court’s equitable power that the effective date of any final approval of Cipla’s ANDA shall be a date that is not earlier than the expiration date of the ’695 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

6. A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Cipla's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '695 patent, prior to the expiration date of the '695 patent, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '695 patent;
7. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;
8. An award of Plaintiffs' costs and expenses in this action; and
9. Such further and other relief as this Court may deem just and proper.

Dated: July 31, 2024

Respectfully submitted,

Charles H. Chevalier

Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4611
cchevalier@gibbonslaw.com

Of Counsel:
David I. Berl
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Counsel for Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, KuDOS Pharmaceuticals Limited, and MSD International Business GmbH